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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,601	08/08/2006	Hiroshi Takaku	2352.008	2223
22	7590 10/03/2007 HENBERG FARLEY & N	EXAMINER		
5 COLUMBIA		CHONG, KIMBERLY		
ALBANY, NY 12203			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary    Examiner		Application No.	Applicant(s)				
Kimberly Chong   1835		10/549,601	TAKAKU ET AL.				
Preiod for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Edentions of time may be available under the provision of 37 CFR 1.35(a). In overt. Inveser, may a reply be limited for state of this communication.  Failur to represent them adjustments the provision of 37 CFR 1.35(a). In overt. Inveser, may a reply be limited the contended period for reply with the state of the communication.  Failur to reply within the store contended period for reply with the state of the communication, even if timely filed, may reduce any search period to the contended period for the state of this communication, even if timely filed, may reduce any reply received by the Office later than the mailing date of this communication.  1) Experiment that a state of the contended period for the state of this communication.  2a) If the state is application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-7 and 9-17 is/are pending in the application.  4) Claim(s) 1-8 and 9-17 is/are pending in the application.  5) Claim(s) 1-8 and 9-17 is/are allowed.  6) Claim(s) 1-6 and 9-15 is/are rejected.  7) Claim(s) 1-6 and 9-15 is/are rejected.  7) Claim(s) 1-7 and 9-15 is/are rejected.  7) Claim(s) 1-8 and 9-15 is/are rejected.  7) Claim(s) 1-8 and 9-15 is/are rejected.  8) The drawing(s	Office Action Summary	Examiner	Art Unit				
ASHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be limely field in after Str. (8) MONTHS from the mailing date of the communication.  Failure to reply within the set or extended period for reply will by statute, cause the application to become ABANDONED (38 U.S.C. § 133). Any reply recited by the field either hin three months after the mailing date of this communication, even if timely field, may reduce any search patient term adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filled on 24 August 2007.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-7 and 9-17 is/are pending in the application.  4a) Of the above claim(s) 7,16 and 17 is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  6) Claim(s) is/are objected to.  8) Claim(s) is/are objected to.  8) Claim(s) is/are objected to.  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 19 September 2005 is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37.CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some "Ol None of:  1. Certified copies of the priority documents have been received		Kimberly Chong	1635				
WHICHEVER IS LONGER, FROM THE MALLING DATE OF THIS COMMUNICATION.  Extensions of them may be available under the provision of 37 CFR 1.136(). In ore were, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period will apply and will apply 60 (6) MONTHS from the malling date of this communication.  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(i).  Proposition of SI U.S. C. § 33).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(i).  Proposition of Si U.S. C. § 330.  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex partle Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-7 and 9-17 is/are pending in the application.  4a) Of the above claim(s) 7.16 and 17 is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  6) Claim(s) is/are objected to.  8) Claim(s) is/are objected to.  8) Claim(s) is/are objected to.  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 19 September 2005 is/are: a) Cacepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abovance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to .See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some *c)—None of:  Cert	• •	ears on the cover sheet with the o	orrespondence address				
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Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	9)☐ The specification is objected to by the Examine	r.					
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The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37.CFR 1.85(a).				
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
a) ☑ All b) ☐ Some * c) ☐ None of:  1. ☑ Certified copies of the priority documents have been received.  2. ☐ Certified copies of the priority documents have been received in Application No  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	Priority under 35 U.S.C. § 119	V.					
<ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		priority under 35 U.S.C. § 119(a	)-(d) or (f).				
2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	,— .						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)							
* See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)	3. Copies of the certified copies of the prior	ity documents have been receive	ed in this National Stage				
Attachment(s)	application from the International Bureau	(PCT Rule 17.2(a)).					
	* See the attached detailed Office action for a list	of the certified copies not receive	d.				
	Attachment(s)	_					
	Notice of References Cited (PTO-892)						
Notice of Draftsperson's Patent Drawing Review (PTO-948)   Paper No(s)/Mail Date	3) X Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal F	·				

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### **DETAILED ACTION**

### Election/Restrictions

Applicant's election without traverse of group I, claims 1-7 and 9-15 in the reply filed on 08/24/2007 is acknowledged.

Claims 16-17 are withdrawn as being drawn to a non-elected invention. Further, claim 7 is withdrawn as being drawn to a non-elected invention. Claim 7 is drawn to a method of treating or preventing HIV comprising administering an oligonucleotide and was erroneously included in group I, drawn to an oligonucleotide targeted to SEQ ID No. 1. Claim 7 clearly belongs with the invention of group II, claims 16-17, and is therefore withdrawn as being drawn to a non-elected invention. MPEP 814 states in part "While every claim should be accounted for, the omission to group a claim, or placing a claim in the wrong group will not affect the propriety of a final requirement where the requirement is otherwise proper and the correct disposition of the omitted or erroneously grouped claim is clear.

# Status of the Application

Claims 1-7 and 9-17 are pending. Claims 1-6 and 9-15 are currently under examination. Claims 7 and 16-17 are withdrawn as being drawn to a non-elected invention.

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#### Information Disclosure Statement

The submission of the Information Disclosure Statement on 008/07/2006 is in compliance with 37 CFR 19.7. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

### **Priority**

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, applicant cannot rely on the foreign priority document to overcome any prior art rejections because translation of the foreign priority document has not been made of record in accordance to 37 CFR 1.55

### Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures: Figures 1 and 7B of the drawings recite sequences that do not have the required sequence identifier in either the drawings or the brief description of the drawings on page 3 of the specification.

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### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6, 10, 11, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed pharmaceutical composition for use *in vitro*, does not reasonably provide enablement for the full scope of a pharmaceutical composition which requires a treatment effect *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Specifically, the language "pharmaceutical composition" in the claims implies a therapeutic or treatment benefit that is not enabled. The *in vivo* inhibition and treatment effects described in the specification at page 10 involve prophetic examples only and have not been reduced to practice. Amendment of the claims to read "A composition comprising the oligonucleotide of claim 1 and a pharmaceutically acceptable carrier or diluent", for example, would obviate this rejection.

In the instant application, the amount of experimentation required to enable a pharmaceutical composition as claimed would be undue based upon the factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) that are considered when making a determination that a disclosure is not enabling that are: the breadth of the claims, the nature of the invention, the state of the prior art, the

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level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

Claims 4, 6, 10, 11, 14 and 15 are drawn to a pharmaceutical composition comprising the oligonucleotide of claim 1 and a pharmaceutically acceptable carrier or diluent and drawn to a pharmaceutical composition for treating or preventing HIV comprising the oligonucleotide of claim 1 and a pharmaceutically acceptable carrier or diluent. Moreover, the claimed pharmaceutical composition of claims 4, 10 and 11 encompasses use *in vivo* and are not limited by or drawn to any particular treatment that is provided by the claimed pharmaceutical composition. Therefore, the scope of claims 4, 10 and 11 is reasonably interpreted as being a pharmaceutical composition that can be used to treat essentially anything in a human by inhibiting the expression of instant SEQ ID NO: 1. Additionally, the scope of claims 6, 14 and 15 are drawn to broadly treating HIV *in vivo*, which includes all pathways and regulatory processes responsible for HIV.

The state of the art at the time of filing, relative to the enablement of the antisense therapies *in vivo*, recognizes that there is a high degree of unpredictability in the art due to obstacles that continue, to the present day, to hinder the therapeutic application of nucleic acids *in vivo* (whole organism) including for example, problems with delivery and target accessibility. The following references discuss the problems of nucleic acid based therapies in reference to the claimed therapeutic antisense method.

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Opalinska et al. 2002 (Nature Reviews, Vol. 1, pp. 503-514) provide a review of the challenges that remain before nucleic acid therapy becomes routine in therapeutic settings and clearly indicate that the art of nucleic acid therapy remains highly unpredictable and unreliable, particularly in vivo. According to Opalinska et al., "Although conceptually elegant, the prospect of using nucleic acid molecules for treating human malignancies and other diseases remains tantalizing, but uncertain. The main cause of this uncertainty is the apparent randomness with which these materials modulate the expression of their intended targets. It is a widely held view that molecule delivery, and selection of which messenger RNA sequence to physically target, are core stumbling blocks that hold up progress in the field" (pg 503). Opalinska et al. also note that .. "[I]t is widely appreciated that the ability of nucleic acid molecules to modify gene expression in vivo is quite variable and therefore wanting in terms of reliability. Several issues have been implicated as a root cause of this problem, including molecule delivery to targeted cells and specific compartments within cells, and identification of sequence that is accessible to hybridization in the genomic DNA or RNA" (pg. 511).

In regards to the delivery of therapeutic nucleic acids, Jen et al. (Stem Cells 2000, Vol. 18, p 307-319) state (pg. 313, second column, second paragraph) "One of the major limitations for the therapeutic use of AS-ODNS and ribozymes is the problem of delivery.... presently, some success has been achieved in tissue culture, but efficient delivery for *in vivo* animal studies remains questionable". Jen et al. outlines many of the factors limiting the application of antisense for therapeutic purposes and concludes (pg.

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315, second column), "Given the state of the art, it is perhaps not surprising that effective and efficient clinical translation of the antisense strategy has proven elusive."

Given this unpredictability, in particular in regards to targeting and delivery of antisense compounds, the skilled artisan would require specific guidance to enable the claimed pharmaceutical composition for use *in vivo*, with a resultant therapeutic and/or preventative outcome, as claimed. The instant specification does not show how one in the art might overcome the obstacles to providing antisense therapy as outlined above or how applicant has overcome the same general obstacles to antisense therapy in the instant invention, commensurate with the full scope of what is now claimed.

In regards to the amount of direction or guidance presented, the disclosure of the specification is insufficient to teach one of skill in the art how to successfully make and use a pharmaceutical composition of the instant invention, as claimed. The specification discloses no *in vivo* treatment of humans using the claimed pharmaceutical composition and no examples of the claimed pharmaceutical composition that has provided a treatment effect, *in vivo*. The disclosure of the specification does provide *in vitro* data of antisense gene inhibition. Applicant has provided *in vitro* examples of compositions that comprise antisense oligonucleotides that inhibit gene expression of cells *in vitro* (see Example 2, for example). However, the field of antisense recognizes that *in vitro* results do not correlate with *in vivo* treatments. Crooke, S. (Antisense Research and Application, Chapter 1, Springer-Verlag, New York. 1998) cautions against extrapolating *in vivo* success from *in vitro* experiments and states on p. 3, paragraph 2, "extrapolations from *in vitro* uptake studies to predictions about *in vivo* 

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pharmacokinetic behavior are entirely inappropriate and, in fact, there are now several lines of evidence in animals and man [that] demonstrate that, even after careful consideration of all *in vitro* uptake data, one cannot predict *in vivo* pharmacokinetics of the compounds based on *in vitro* studies [references omitted]."

In regards to the amount of experimentation that would be required to enable the instantly claimed pharmaceutical composition, because no functional species of the claimed pharmaceutical composition is disclosed in the specification and no specific guidance is provided that would enable the skilled artisan to make and use the claimed pharmaceutical composition, an undue quantity of de novo trial and error experimentation would be required for the skilled artisan to practice the claimed invention. This undue, de novo trial and error experimentation would require, at a minimum, determining what treatments could be provided by the instantly claimed pharmaceutical composition, a demonstration that the claimed pharmaceutical composition will provide the determined treatment effect and the determination of modes of delivery in vivo such that the pharmaceutical composition could be provided, at a significant level for a sufficient amount of time to produce the desired treatment effect as claimed, for example. Given the unpredictability in the field of antisense, such experimentation would not be routine. Based on the lack of specific guidance in the specification regarding the direction in which the experimentation should proceed, even if the de novo experiments required were considered routine by those of skill in the art, the more or less standard nature of each experiment would be outweighed by the sheer quantity of de novo undue trial and error experimentation required to determine how to

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practice the method of the instant invention. Moreover, even through such undue experimentation, the skilled artisan would not even expect to be successful for the broad scope of treatment as claimed.

In conclusion, due to the nature and breadth of the claimed invention as a pharmaceutical composition for use *in vivo* to provide a treatment, the degree of unpredictability in the art of antisense therapy, the lack of guidance as to what particular species of pharmaceutical composition would provide a treatment effect and what that treatment effect would be, the need to screen multiple species of said pharmaceutical composition so as to allow identification of any particular species as functional and the quantity of *de novo* experimentation necessary to discover the above, an undue amount of *de novo* experimentation would be required in order to make and use the claimed pharmaceutical composition.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schubert et al. (U.S. Patent No. 5,847,096).

Claims 1 and 2 are drawn to an oligonucleotide consisting of a nucleotide sequence that is complementary or an oligonucleotide comprising a nucleotide

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sequence which specifically hybridizes to a nucleotide sequence consisting of at least 15 successive nucleotides of SEQ ID No. 1 in the range of nucleotides 6 to 44.

Schubert et al. teach an oligonucleotide sequence consisting of a nucleotide sequence that is complementary to at least 15 nucleotides of SEQ ID No. 1 in the range of nucleotides 6 to 44 (see attached sequence alignment). The instant specification discloses on page 6 that specific hybridization of an oligonucleotide encompasses an oligonucleotide that hybridizes with at least 15 nucleotides of SEQ ID No. 1. Therefore, for prior art purposes, "specifically hybridizes" is interpreted to mean an oligonucleotide that is complementary to at least 15 nucleotides of the instantly claimed sequence.

Thus, Schubert et al. anticipates the instant claims 1 and 2.

# Claim Rejections - 35 USC § 102 or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 5 and 12 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Schubert et al. (U.S. Patent No. 5,847,096).

Claims 5 and 12 are drawn to an anti-HIV agent consisting of a nucleotide sequence that is complementary or an oligonucleotide comprising a nucleotide sequence which specifically hybridizes to a nucleotide sequence consisting of at least 15 successive nucleotides of SEQ ID No. 1 in the range of nucleotides 6 to 44.

Schubert et al. teach an oligonucleotide sequence consisting of a nucleotide sequence that is complementary to at least 15 nucleotides of SEQ ID No. 1 in the range of nucleotides 6 to 44 (see attached sequence alignment). The instant specification discloses on page 6 that specific hybridization encompasses an oligonucleotide that hybridizes with at least 15 nucleotides of SEQ ID No. 1. Therefore, for prior art purposes the term, "specifically hybridizes", is interpreted to mean an oligonucleotide that is complementary to at least 15 nucleotides of the instantly claimed sequence. Further, the instant specification discloses that an anti-HIV agent is an oligonucleotide agent that is capable of inhibiting the production of HIV.

The oligonucleotide sequence taught by Schubert et al. meets the structural limitations of the instant claims and therefore would be considered an anti-HIV agent that is capable of hybridizing to the claimed SEQ ID No. 1 and inhibit the production of HIV, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both

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35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the instant claims are anticipated or obvious over Schubert et al.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mourich et al. (US 2005/0222068) in view of Galderisi et al. (J. Cellular Physiology 1999, Vol. 181: 251-257).

Claims 1-6 and 9-15 are drawn to an oligonucleotide consisting of a nucleotide sequence that is complementary or an oligonucleotide comprising a nucleotide sequence which specifically hybridizes to a nucleotide sequence consisting of at least 15 successive nucleotides of SEQ ID No. 1 in the range of nucleotides 6 to 44 wherein at least one internucleotide bond is a phosphorothioate bond and drawn to an anti-HIV

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agent and further drawn to a pharmaceutical composition comprising the claimed oligonucleotide.

Mourich et al. teach an antisense compound that is complementary and specifically hybridizable to at least 15 successive nucleotides of SEQ ID No. 1 (see attached sequence alignment and SEQ ID No. 18). Mourich et al. teach the antisense compound inhibits viral replication of HIV in cells (see paragraph 0075) and teach an embodiment of a composition comprising an antisense compound and a pharmaceutically acceptable diluent such as water or PBS (see paragraph 0151). Mourich et al. teach said antisense compounds can be modified to increase nuclease stability and cellular uptake (see paragraphs 0113-0118), but does not teach the internucleotide bonds of the antisense sense molecule comprise phosphorothioate bonds.

Galderisi et al. teach antisense compounds comprising phosphorothioate bonds and teach compositions comprising said antisense compounds for delivery to cells and teach phosphorothioate bonds are one of the most frequent variants of antisense oligonucleotides, particularly for therapeutic applications (see page 252, column 2).

It would have been obvious to one of skill in the art to incorporate phosphorothicate bonds taught by Galderisi et al. into the antisense compound taught by Mourich et al.

One of skill in the art would have been motivated to use phosphorothicate internucleotide bonds because Galderisi et al. teach such chemical modifications have enhanced or conferred nuclease resistance to antisense molecules. Properties such as

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nuclease resistance and increased cellular uptake are regarded by one of skill in the art as extremely beneficial properties of therapeutic oligonucleotides (see page 254).

Moreover, one would have been motivated to specifically use phosphorothioate bonds given that Galderisi et al. teach such phosphorothioate modified oligonucleotides are the most widely used molecules in antisense methodologies. Further given that antisense oligonucleotides have emerged as powerful new agents in antiviral therapeutics as demonstrated by the success of a phosphorothioate antisense oligonucleotide targeted against cytomegalovirus (see page 255, column 1), one of skill in the art would have clearly wanted to increase the antisense compounds nuclease resistance and cellular uptake by incorporating chemical modifications such as phosphorothioate bonds.

Finally, there would have been a reasonable expectation of success at incorporating the phosphorothicate bonds into an antisense oligonucleotide because Galderisi et al. outlines the success of such modifications in antisense oligonucleotide methodologies.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/ Examiner AU 1635

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<!--StartFragment-->US-10-971-959B-18/c
; Sequence 18, Application US/10971959B
; Publication No. US20050222068A1
; GENERAL INFORMATION:
  APPLICANT: Mourich, Dan V.
  APPLICANT: Iversen, Patrick L.
  TITLE OF INVENTION: Method and Antisense Composition for Selective Inhibition of HI
  TITLE OF INVENTION: Infection in Hematopoietic Cells
  FILE REFERENCE: 50450-8063.US00
  CURRENT APPLICATION NUMBER: US/10/971,959B
  CURRENT FILING DATE: 2004-10-21
  PRIOR APPLICATION NUMBER: US 60/514,064
; PRIOR FILING DATE: 2003-10-23
; NUMBER OF SEQ ID NOS: 47
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US-10-971-959B-18
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  GENERAL INFORMATION:
    APPLICANT: SCHUBERT, MANFRED, HARMISON II,
    APPLICANT: GEORGE G., CHANG-JIE, CHEN, BANJERJEA, AKHIL
    TITLE OF INVENTION: DEFECTIVE, INTERFERING
    TITLE OF INVENTION: HIV PARTICLES
    NUMBER OF SEQUENCES: 77
    CORRESPONDENCE ADDRESS:
     ADDRESSEE: MORGAN & FINNEGAN, L.L.P.
      STREET: 345 PARK AVENUE
      CITY: NEW YORK
      COUNTRY: U.S.A.
      ZIP: 10154
    COMPUTER READABLE FORM:
      MEDIUM TYPE: Diskette
      COMPUTER: IBM PC COMPATIBLE
      OPERATING SYSTEM: PC-DOS/MS-DOS
      SOFTWARE: WORD PERFECT 5.1
    CURRENT APPLICATION DATA:
      APPLICATION NUMBER: US/08/418,848A
      FILING DATE: 07-APR-1995
      CLASSIFICATION: 526
    PRIOR APPLICATION DATA:
    APPLICATION NUMBER: 07/936,849
      FILING DATE: 28-AUG-1992
      CLASSIFICATION: 526
    ATTORNEY/AGENT INFORMATION:
     NAME: RICHARD W. BORK
      REGISTRATION NUMBER: 36,459
      REFERENCE/DOCKET NUMBER: 2026-4091US2
    TELECOMMUNICATION INFORMATION:
      TELEPHONE: 212-758-4800
      TELEFAX: 212-751-6849
      TELEX: 421792
  INFORMATION FOR SEQ ID NO:
    SEQUENCE CHARACTERISTICS:
      LENGTH: 20 base pairs
      TYPE: nucleic acid
      STRANDEDNESS: single
      TOPOLOGY: linear
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